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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,964	07/11/2000	Walter Schubert	S159 1020	1538

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Womble Carlyle Sandridge & Rice
P O Box 720601
Atlanta, GA 30358-2601

EXAMINER

PADMANABHAN, KARTIC

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 11/04/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/613,964

Applicant(s)

SCHUBERT, WALTER

Examiner

Kartic Padmanabhan

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14 and 16-25 is/are pending in the application.
- 4a) Of the above claim(s) 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 14 and 16-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 16-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. The recitation of “capable” in claim 16 renders the claim vague and indefinite. It is unclear, with this terminology, if the object holder actually receives a target structure or not. In addition, the recitation of a duct being defined by the object holder and the stretchable sheet is also vague and indefinite. In what way is the duct defined in this manner. The precise arrangement of the recited elements has not been adequately recited in the claim. Applicant should also delete the comma after “stretchable” in part c) of the claim.
4. Claim 23 recites the limitation "said at least one stretchable, non-elastic sheet". There is insufficient antecedent basis for this limitation in the claim. The parent claim only refers to a stretchable sheet. The recitation of the “stretchable, non-elastic sheet” also renders the claim vague and indefinite. How can something be stretchable but not elastic? According to Merriam Webster’s Collegiate Dictionary Tenth Edition, one definition of elastic is “capable of being easily stretched.” Similarly, a definition of stretch is “elastic.” Claim 23 is also rejected as vague and indefinite for the recitation of “at least one stretchable” in line 1 of the claim because applicant has not recited the element this phrase is describing.

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5. Claims 24 and 25 are rejected as vague and indefinite for the recitation of a “rail” because the intended meaning of this limitation is unclear.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 16-18 and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Andreovski et al. (US Pat. 5,882,903). The reference discloses an assay system comprising a first assembly (object holder) comprising a reaction chamber (target structure) and a first fluid exchange channel that provides fluid communication to and from the reaction chamber. The system also comprises a second assembly for temperature control of the reaction chamber (col. 27, lines 35-54). In addition, the reaction chamber has a cover formed of a deformable material, wherein the cover is preferably formed of membrane films that are stretchable and flexible. The cover is, at a minimum, disposed indirectly on the object holder. When the cover is made of this deformable material, a plunger may be used to facilitate fluid transfer to a fluid exchange port that flows into an alignment chamber. The device of the reference may also comprise a pump. Also, the reference discloses that the assay system of the reference may take a number of configurations, including square and rectangular. Since a rail is simply interpreted as a rod-like support structure and the deformable cover inherently contacts the sides of the object holder, in the case of a square or rectangular configuration, the contact of the deformable cover to the sides of the object holder are sufficient to meet the limitation of a rail.

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Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andreovski et al. (US Pat. 5,882,903) in view of Freeman (US Pat. 5,958,760).

Andreovski et al. teach an assay system, as previously discussed under 35 USC 102.

However, the reference does not teach the use of a Peltier element or a vessel.

Freeman teaches a sample-processing device comprising a support cell made up of a sealed chamber provided with a fluid inlet and outlet for introduction and removal of fluids used in sample processing (col. 2, lines 7-16). Typically, the support cell will be provided with a Peltier device, which may be used to heat or cool the cell to temperatures in the range of 4-100 degrees Celsius (col. 4, lines 13-22). The processing fluids are preferably held in reservoirs, each of which is attached to pump means (col. 4, lines 39-49 and col. 5, lines 3-11). After the processing fluids have been used, the waste is collected in a common waste duct that empties

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into a glass beaker (col. 10, lines 37-41). The duct of the reference is plastic, which is interpreted as stretchable.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the Peltier element and collection vessel of Freeman with the device of Andrevski et al. One would have been motivated to do so because the Peltier element of Freeman could have easily been used as the temperature control element of Andrevski et al. In addition, one would have been motivated to use the collection vessel of Freeman et al. with the device of Andrevski et al. to collect waste in a convenient manner.

11. Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andrevski et al. (US Pat. 5,882,903) in view of Freeman (US Pat. 5,958,760), as applied to claims 19-20 above, and further in view of Teppke et al. (US Pat. 5,960,640).

Andrevski et al. and Freeman teach a modified sample-processing device, as discussed above. However, the references do not teach the use of a vessel Peltier element.

Teppke et al. teach a cryostatic microtome comprising a coolable specimen holder and knife holder. One way in which the specimen holder and knife holder can be cooled is through the use of Peltier elements in the specimen holder and knife holder (col. 2, lines 38-45). Capillaries are provided which are connected to the evaporator in the specimen holder (col. 6, lines 43-50).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use multiple Peltier elements as taught by Teppke et al. with the modified device of Andrevski et al. and Freeman. Although Freeman only teaches the use of Peltier elements with support cells, incorporating one with the discharged liquid container simply represents an

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optimization of assay protocol. If one wished to use the discharged liquid for another purpose or at a later time, one would have been motivated to maintain the liquid at a suitable temperature, which can be done with a cooling Peltier element. For example, Teppke et al. uses two Peltier elements because such an arrangement allows for independent temperature control of various components of the device.

12. Claims 16-19 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hancock et al. (US Pat. 5,716,825).

The reference teaches a nucleic acid analysis system comprising a sample preparation compartment having access ports. The system may be constructed using a plastic polymer. The compartment is preferably enclosed by a cover formed of transparent material to allow observation of sample handling. The cover includes apertures spatially aligned with wells to form access ports when the cover is attached to the support. The device of the reference may also include valveless pumps. In addition, a Peltier element may be positioned to provide temperature control to the reaction zone of the device (Cols. 9-10). Since a rail is simply interpreted as a rod-like support structure and the cover inherently contacts the sides of the compartment, the contact of the cover to the sides of the compartment are sufficient to meet the limitation of a rail. However, the reference does not teach a cover made of a stretchable sheet.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use a stretchable sheet as the cover of Hancock et al. The reference only requires the cover to be transparent and does not limit the composition of the cover in any way. As such, one could have used a cover made of some plastic material as the cover with the device

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of the reference with a reasonable expectation of success. Since plastic is relatively cheap, use of this material may reduce the cost associated with the practice of the invention.

Response to Arguments

13. Applicant's arguments filed July 29, 2002 have been fully considered but they are not persuasive.

14. It is first noted that neither Andreovski nor Freeman were ever applied under 35 USC 102(a), as applicant states. Rather, Freeman was applied under 35 USC 102(e), and Andreovski was, and continues to be applied under 35 USC 102(b).

15. Applicant's arguments that the Andreovski reference does not disclose the claimed invention merely amounts to an allegation of patentability without showing how the reference does not disclose all the elements of the claims to which it was applied. As discussed under 35 USC 102, the examiner continues to believe that the reference does indeed anticipate the claims to which it was applied.

16. Applicant's arguments with respect to the Freeman reference are moot, as it has been withdrawn under 35 USC 102, and has been applied in combination under 35 USC 103.

17. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Teppke is only relied upon for the teaching of a vessel Peltier element, and

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not for any other teaching. The fact that the device of Teppke is different than the devices of Andrevski and Freeman is irrelevant, as long as motivation exists to use the Peltier element of Teppke with the combination of Andrevski and Freeman, which the examiner believes there is. The ability to independently control the temperature of various parts of the device provides sufficient motivation to use a second Peltier element.

18. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

Claims 16-25 are rejected.

Reference: Parce et al. is cited as art of interest for teaching an analysis system.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641



October 29, 2002



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

11/01/02